APMSIDC

TENDER NO: 136

PROCUREMENT OF SURGICAL CONSUMABLES FOR PROGRAM

APMSIDC :: DRUGS WING





TENDER NO: -136/APMSIDC/MEDICINE WING/2021-22

TENDER FOR SUPPLY OF SURGICAL CONSUMABLES

То

ANDHRA PRADESH MEDICAL SERVICES & INFRASTRUCTURE DEVELOPMENT CORPORATION

ANDHRA PRADESH MEDICAL SERVICES & INFRASTRUCTURE DEVELOPMENT CORPORATION

(AN ENTERPRISE OF GOVT. OF A.P.), Plot No.9, Survey No.49, IT Park, Mangalagiri, Guntur District – 522 503. ANDHRA PRADESH URL: <u>http://msidc.ap.nic.in</u>

ONLINE TENDER FOR THE SUPPLY OF SURGICALS TO APMSIDC

| S. No | Information | Details | |
|-------|---|---|--|
| 1 | Bid Reference | 136/APMSIDC/MEDICINE WING/ 2021-22 | |
| 2 | Date and time for downloading bid document | From 30-Mar-2022, 05:30 pm | |
| 3 | Prebid Meeting/Queries | At Conference Hall, APMSIDC, 2 nd Floor, @ 11.00AM on 04- Apr-2022 and also Submit your Query through email till 04- Apr-2022 05:00 PM to email tenders.apmsidc@gmail.com with subject : Prebid Queries for T NO 136 (SUR-HEP-B,C) | |
| 4 | Last date and time for uploading Documents | 08-Apr-2022 at 5.00 pm | |
| 5 | Date and time of opening of Online technical bids | 08-Apr-2022 at 5.01 pm | |
| 6 | Last date and time of submission of offline documents and SAMPLES | 08-Apr-2022 at 5.00 pm | |
| 7 | Tender Processing Fee | The bidder shall remit processing fee(Non-Refundable Rs. 11,800/- (Rs.10,000+ 18%GST) in the form of Demand Draft in the name of The Managing Director, APMSIDC, Mangalagiri. | |
| 8 | Control DC, Mangalagin.Earnest Money DepositThe Earnest Money Deposit (EMD) in the form of Demand Draft only for Rs.3,00,000/- in favour of Managing Director, APMSIDC, Mangalagiri, Gun district | | |
| 9 | E-mail | tenders.apmsidc@gmail.com, apmsidc.gm@gmail.com | |
| 10 | Contact number | General Manager- Drugs: 8978680705 Pharmacist : 9966878700 | |
| 11 | APMSIDC Bank Details | Account Holder Name: The Managing Director, APMSIDC, Account No : 142410011000314, IFSC Code : ANDB0000366, Bank Name : Andhra Bank, Branch Name : Mangalagiri, Guntur District, Andhra Pradesh. | |

The tender document can be downloaded free of cost from the e-Procurement Portal https://tender.apeprocurement.gov.in/ and from the website of APMSIDC <u>www.msidc.ap.nic.in</u>.

ONLINE TENDER FOR THE SUPPLY OF SURGICAL CONSUMABLES TO APMSIDC

APMSIDC is responsible for procurement and supply of all essential Medicines & Surgical Consumables to the Government Health facilities of A.P., to ensure availability of medicines on free of cost. The main functions of the Corporation are Construction & Maintenance of Hospital Buildings. Further, the Procurement and distribution of Drugs, Surgical& Consumable and Equipment is also entrusted to this Corporation by the Government (Medical and Health Department). The Corporation is functioning on No Profit and No Loss basis.

Purchaser/Tender Inviting Authority – Managing Director, APMSIDC, Mangalagiri-522503, Guntur District, Andhra Pradesh(hereinafter referred as Tender Inviting Authority unless the context otherwise requires).

Purchaser/Tender Accepting Authority – Managing Director, APMSIDC, (hereinafter referred as APMSIDC unless the context otherwise requires).

Tender Inviting Authority invites Tender for the supply of Surgical Consumables to APMSIDC.

GENERAL CONDITIONS :

• (a) At any time prior to the last date of submission of online bid, Tender Inviting Authority may, for any reason, whether on own initiative or in response to a clarification requested by a prospective Tenderer, may modify the condition in Tender documents by an amendment uploading on website on <u>msidc.ap.nic.in;</u> and AP Procurement portal i.e. <u>apeprocurement.gov.in</u> will be binding on them. In order to provide reasonable time to take the amendment into account in preparing their bid, Tender Inviting Authority may at discretion, extend the date and time for submission of online bid.

(b) Any person who has downloaded the tender document should watch for amendment, if any, on the website <u>msidc.ap.nic.in;</u> and AP Procurement Portal i.e. <u>apeprocurement.gov.in</u> for which APMSIDC will not issue any separate communication to them.

- During tender or price agreement period, if L1 bidder is debarred/deregistered/blacklisted/banned by any Central Government or state Government or its procurement agencies due to quality failure, APMSIDC may purchase the drugs/Items from other qualified bidders who shall match the price of L1 or may go for fresh tender as per discretion of APMSIDC.
- All the bidders are instructed to submit a copy of documents that are submitted online on or before due date in sealed cover.

SPECIAL CONDITIONS

- (i) Bids shall be submitted **online** only at procurement portal website:<u>https://apeprocurement.gov.in</u>. Manual bids shall not be accepted except for the original documents/instruments as mentioned in tender document.
- (ii) Bidders are advised to check the website of APMSIDC: <u>msidc.ap.nic.in</u> and Procurement portal website <u>https://apeprocurement.gov.in</u> prior to closing date of submission of tender for any corrigendum, addendum, or amendment to the tender document.
- (iii) Online Bids and price bid will be submitted on AP e-procurement portal i.e. <u>https://tender.apeprocurement.gov.in/</u>
- (iv) The price bid shall be valid for a period of 120 days from the date of opening of Technical Bid. Prior to the expiry of the bid validity, the Tender Inviting Authority may request the Tenderers to extend the bid validity for further period as deemed fit on their original quoted prices and all terms & conditions.

ELIGIBILITY CRITERIA :

- The tender document shall be downloaded from the websites msidc.ap.nic.in; and portal i.e.apeprocurement.gov.in. The bidder shall remit **processing fee (Non Refundable) Rs. 11,800/- (Rs.10,000+ 18%GST)** in the form of Demand Draft in the name of The Managing Director, APMSIDC, Mangalagiri.
- The Earnest Money Deposit referred to shall be **Rs. 3 lakh. The Earnest Money** Deposit shall be paid in the form of Bank Guarantee or Demand Draft in favour of APMSIDC, payable at Mangalagiri. In case EMD in form of Bank Guarantee, Irrevocable Bank Guarantee in favour of APMSIDC from any Nationalized/scheduled Bank should be valid for a period beyond 6 months from the date of tender opening. The format of Bank Guarantee. APMSIDC will not pay interest on any deposit held in the form of EMD.
 - a. The tender submitted without sufficient EMD will be summarily rejected.
 - b. The Earnest Money Deposit (EMD) of the unsuccessful bidders will be returned after finalization of tender with eligible bidder.
 - c. The Earnest Money Deposit (EMD) will be forfeited, if the tenderer withdraws his bid any time after opening of price bid / non submission of

Performance security within the period prescribed/non supply of surgical consumables.

- d. The Earnest Money Deposit (EMD) will be forfeited, in case of the lowest bidder, fails to execute the contract or deposit the performance security deposit within the stipulated time. The EMD shall be forfeited if any of the documents found incorrect.
- e. SSI units situated in AP state are exempted from the payment of EMD.(necessary certificates to be submitted).
- (i)Valid manufacturing license/Licenses for manufacturing the products issued by concerned authorities. If any product is declared as new drug/Item by CDSCO, then the firm should have valid license / product permission from DCG India along with the state license. As per the Govt. Memo No.426212/H2/2016, HM&FW(H2) Dept. dated 01-02-2017 approval of Central Drugs Standard Control Organization (CDSCO) by the firms/bidders is mandatory for all antibacterial (Coated) absorbable sutures.

(ii)Valid import license if the product is imported. (Under Form – 10 in case of items notified as drugs) Valid Product license (For items notified as Drugs it is from DCA/DCG(I) and for Non-Drug items it is from concerned statutory Departments).

(iii)Valid licenses for distribution of products (in case of authorized distributors wherever applicable) (For items notified as Drugs it is from DCA and for Non-Drug items it is from concerned statutory Departments).(Non drugsauthorization from manufacture and manufacture license) If pesticides and larvicides license issued by Agriculture department

Valid ISO/BIS/CE or any other quality assurance certificates issued by concerned authorities. **QMS certificate allowed the product approved by CDSCO which GMP is not issued by CDSCO**

• A original certificate from their C.A. (Chartered Accountant) or Company Secretary that:

Average Annual turnover of manufacturer in the last continuous three years i.e. 2017-18, 2018-19 and 2019-20 **or** 2018-19, 2019-20 and 2020-21 shall not be less than Rs.5 Crores and for authorized Distributors shall not be less than Rs.10 Lakhs.

II.(a)Latest Non-conviction Certificate issued by the licensing authority of the State certifying that the firm/company has not been convicted certificate issued

by Charted Account. Not less than 12 months from the date of commencement of tender .Drug item –NCC issued by Drug control department, Non drugs issued by CA of the firm

(b)Tender should not be submitted for the product(s) for which the firm / company has been blacklisted/debarred/de-registered/banned by any State Government / Central Government / its Drug procurement agencies due to quality failure of the products *at the time of submission of online bid.*

I During the validity of the tender, if the firm / Company is blacklisted/debarred/de-registered/banned by any State Government / Central Government / its Drug procurement agencies / convicted by any Court of law in India, it shall be intimated to APMSIDC along with relevant authentic document by the tenderer firm/ company within one month otherwise a penalty of Rs 1,00,000/-shall be imposed on the firm by APMSIDC.

(d)The tenderer should confirm that they have read tender document including Amendment(s)to Tender document (if any) along with terms and condition and these terms and condition of tender document including Amendment(s) to Tender document (if any) are acceptable unconditionally to them.

TECHNICAL BID

The Tenderer should upload the following documents while submitting technical bid. (Scanned copies of each page of all documents should be uploaded while submitting Technical bid).

- (a) The tenderers are required to upload scanned undertaking on stamp paper duly notarized by authorized signatory (ANNEXURE – II) confirming each clause mentioned in Section 2 of eligibility criteria.
- (b) In case the bidder is Importer, they may strike the clause or part of clause not applicable in their case. <u>The surgical &consumables indicated in this undertaking shall only be considered for evaluation and opening of price bid.</u>
- (c) Samples and Offline documents in sealed cover should be submitted to APMSIDC, Mangalagiri on or before the scheduled date given in Tender Document.
 - i. EMD instrument should be submitted to APMSIDC, Mangalagiri on or before the schedule date of technical bid opening.
 - ii. The tenderers are required to upload a certificate from the C.A. (Chartered Accountant) or Company Secretary as per **ANNEXURE IV. Or any other authorized format for imported products.**

- iii. Authorization letter nominating an officer of the Tenderer on the printed letter head of the company to transact the business with the APMSIDC to be uploaded.
- iv. And all the documents that are to be submitted as per the tender condition.
- (d) The Tenderer should upload Scanned copy of valid Drug/Kit Manufacturing License/Authorized **Distributor License** for the product.
- (e) Scanned copy of import license (in Form 10 with Form 41), as per Rule 122A of the Drugs and Cosmetics Act 1940, if the product is imported should be uploaded. The license must have been renewed up to date. A copy of a valid license for the sale of Drugs/Items imported by the firms issued by the State Licensing Authority shall be uploaded. Original documents should be produced for verification when demanded.
- (f) Documents, if any, to show that the manufacturing unit/importer has been recognized by any other Indian / International Standard Organizations etc. as applicable. Importer should upload WHO-GMP certificate of manufacturer. /ISO/CE/BIS certificates
- (g) A Checklist shall be uploaded with technical bid. If a company/firm has two or more separate manufacturing units at different sites / States, which are not separate entities then the company will be allowed to submit only one tender for all units but necessary document regarding separate manufacturing units will be uploaded as a separate set with the same tender. However, one bidder will be allowed to submit only one offer for one product.
- (h) All the documents uploaded should also be signed by the authorized official of the Tenderer.

PRICE BID

Price Bid of the Tenderer.

- 3 The Tenderer shall fill in the rate per unit size inclusive of GST (Can provide Rate quoted information in Remarks column)
- (ii) Determination of L1 bidder:

In determining the lowest evaluated price, the rate quoted per unit size inclusive of GST as indicated in price bid shall be taken into consideration and lowest landed price will be taken into consideration for determination of L1 Bidder.

(iii) In case no information is given on GST, it shall be presumed that rates are inclusive of GST and no GST shall be charged by them under any circumstances.

OPENING OF TENDER

- After the completion of Technical evaluation preliminary objections will be published on APMSIDC portal www.msidc.ap.nic.in for replies from firms. After scrutiny of these remarks by the technical committee final evaluation will be done.
- Only the technically qualified firms in the bid will be eligible for opening of price bid.

OTHER CONDITIONS

(i) The details of the required surgical & consumables are shown in ANNEXURE

 VIII. The tender quantity mentioned herein is not a fixed procurement quantity and it is only a tentative requirement and may be increased or decreased by APMSIDC, at its discretion, depending on its actual need. Though the tentative quantity is indicated in the price agreement, the APMSIDC, will confirm the actual requirement then and there through purchase order/orders. The tenderers shall supply the surgical consumables only on the basis of the purchase order issued from time to time within validity of contract period by the APMSIDC. Any supply without a valid purchase order will not be acceptable by APMSIDC and the APMSIDC shall not be responsible for any loss on this account.

(ii) The Tenderer shall fill in manufacturing capacity per year in units, Shelf life in months and manufacturing batch size in units for each quoted surgical consumable in required column of **ANNEXURE –V and upload along with technical bid.** In case the bidder is Importer, the importer is required to sign and upload ANNEXURE V on behalf of the exporter which would be supported by documentary evidence provided by the manufacturer.

(iii)However, once the purchase order/orders is/are issued by the APMSIDC, the tenderer shall no trenege from the commitment of supplying the quantity mentioned in the acceptance of tender for price agreement.

(iv)The rates quoted shall not be varied with the ordered quantity during the full contract period.

• Rates (inclusive of Customs duty, packing & forwarding charges, transportation, insurance and any incidental charges, all taxes, GST) should be quoted for each of the required surgical consumables separately on door delivery basis to all 13

Central Drug stores located in District headquarters of AP state according to the unit ordered. Tender for the supply of surgical consumables. With cross conditions like "AT CURRENT MARKET RATES" shall not be accepted. Handling, clearing, transport charges etc., will not be paid separately. The delivery should be made as stipulated in the purchase order placed with Tenderers.

• Each bid must quote not only the unit rate but also the total value of each item quoted for supply in the respective columns. The aggregate value of all the items quoted in the tender shall also be furnished.

FALL CLAUSE:

- If at any time during the execution of the contract, the controlled price becomes lower or the supplier reduces the sale price or sells or offers to sell such stores, as are covered under the contract, to any person / organization including the purchaser or any department of Central government/state Govt. or its procurement agencies at a price lower than the price chargeable under the contract, he shall forthwith notify such reduction or sale or offer of sale to the purchaser and the price payable under the contract for the stores supplied after the date of coming into force of such reduction or sale or offer of sale shall stand correspondingly reduced.
- The rates quoted and accepted will be binding on the Tenderer for the full contract period of two years and any increase in the price will not be entertained till the completion of this contract period. Accordingly, this clause will be applicable for all orders placed during the contract period. However, Price agreement validity period may be extended for period up to further one year at same rate, terms & conditions with the consent of the supplier.
- No Tenderer shall be allowed at any time and on any ground, whatsoever it may be, to claim revision or modification in the rates quoted by them. Representation to make correction in the tender documents on the ground of Clerical error, typographical error, etc., committed by the Tenderers in the Bids shall not be entertained after submission of the tenders. Cross Conditions such as "SUBJECT TO AVAILABILITY", "SUPPLIES WILL BE MADE AS AND WHEN SUPPLIES ARE RECEIVED" etc., will not be entertained under any circumstances and the tenders of those who have mentioned such conditions shall be treated as incomplete and accordingly the Tender will be summarily rejected.
- The Tenderer shall allow inspection of the factory at any time after the opening of technical bid and during the entire contract period by a team of Experts/Officials nominated by the Tender Inviting Authority for the purpose. The Tenderer shall extend necessary cooperation to such team in inspection of the manufacturing process, quality control measures adopted etc., in the

manufacture of the items quoted. If Company/Firm does not allow for any such inspection, their tenders will be rejected. If any such situation arises after placement of contract, the same shall be cancelled at the firm's risk cost.

• "AP Govt Supply – Not for Sale" should to be printed on each unit/label by the successful bidders. However, this is exempted for imported items.

ACCEPTANCE OF TENDER

 (i). In case, L2 bidder does not agree to match L1 rate, 100% tender quantity shall be awarded to L1 bidder. The purchase order shall be issued to L1 bidder and L2 bidders simultaneously as per discretion of APMSIDC depending upon requirement. In case, order is placed only on L1 bidder and if they fail to supply in stipulated time or due to quality failure, the purchase order shall be issued to L2 bidder.

(ii). Negotiation if required will be done at APMSIDC premises.

- APMSIDC reserves the right to accept or reject the tender for the supply of all or any one or more items of the s tendered for in a tender without assigning any reason.
- **APMSIDC** also reserves right to place one-time purchase order for certain quantity of any surgical consumables even without price agreement, for such surgical consumables' suppliers are required to pay performance security deposit @ 5 % of value of order of such item in the form of DD.
- The acceptance of the tenders for Price Agreement for two years period will be communicated to the Tenderers.

PERFORMANCE SECURITY DEPOSIT

- Performance Security Deposit:
- On being informed about the acceptance of the tender for 2 years price agreement, the successful tenderer shall be required to pay a Performance Security Deposit of 5% of the contract value subject to a maximum of Rs.10 lakhs per product in the form of *Demand Draft* drawn infavor of MD, APMSIDC Mangalagiri from any nationalized/scheduled Bank.
- The Tenderer shall not, at any time, assign, sub-let or make over the contract or the benefit thereof or any part thereof to any person or persons whatsoever.
- All notices or communications relating to and arising out of this price agreement or any of the terms thereof shall be considered duly served on or given to the Tenderer if delivered to him or left at the premises, places of business or abode as provided by the tenderer.

- If the lowest selected Tenderer fails to deposit the required Performance Security Deposit (PSD) within the time specified or withdraws the tender, after the intimation of the acceptance of the tender or owing to any other reasons to undertake the contract, the contract will be cancelled and the Earnest Money Deposit deposited by the tenderer along with the tender shall stand forfeited by the APMSIDC and the firm will also be liable for all damages sustained by the APMSIDC apart from blacklisting and other penal actions.
- The performance security deposit of supplier will be returned after the end of rate contract period by APMSIDC only after the supplier has given undertaking to replace items supplied and indemnify APMSIDC against any losses on account of quality parameters.
- **SSI-**units situated in A.P are exempted from payment of Performance Security Deposit.

METHODOLOGY FOR PLACING ORDERS

For the above purpose the following procedures will be adopted

- (a) After the conclusion of Price Bid opening, the rates offered by tenderers for each product are evaluated and lowest acceptable rate (L1 Rate) arrived at is declared and that tenderer is informed.
- (b) The successful Tenderer is eligible for the placement of Purchase Orders only after depositing the required amount as Performance Security.
- (c) If two or more than two Tenderer's are declared as lowest suppliers for the same item(s), such Tenderers are eligible for price agreement and the placement of Purchase Orders for such item(s) for which they are declared as lowest. Placement of order shall be shared equally amongst these bidders subject to their manufacturing capacity.
- (d) In the case of purchase of goods where the quantity offered at the lowest price is less than the total quantity required, the APMSIDC may, after placing orders with the lowest evaluated Tenderer for the entire quantity offered by such Tenderer subject to his ability to supply, require all the other eligible Tenderers who participated in the tender and offered a price higher than that offered by the lowest evaluated Tenderer, to submit sealed offers of the quantity they would be willing to supply at the price quoted by the lowest evaluated Tenderer, and thereafter place orders for the remaining required quantity with all those who match the lowest evaluated price such that those who bid lower prices in the original tender get a higher priority for supply.

- (e) If a supplier fails to execute supply order (0% execution) Performance Security Deposit of the product mentioned in purchase order shall be forfeited.
- (f) Notwithstanding anything contained in para (e) above, the supplier, after committing the default in supply either partly or fully, can inform the APMSIDC about his willingness to execute the Purchase Order during the tender period. The APMSIDC at discretion may consider the willingness of the supplier on merit. However, such supplies will be subjected to the levy of Liquidated Damages, unexecuted fine and other penalties as stipulated in the tender document, price agreement and purchase order.
- (g) The supplier shall start supply of the surgical consumables required by APMSIDC at 13 Central Drug Stores (CDS), in Andhra Pradesh or any other place decided by APMSIDC within the stipulated period.
- (h) The surgical consumables supplied in excess of the ordered quantity shall not be accepted and the supplier shall take back the excess at their cost. APMSIDC will not be responsible for the loss to the supplier and will not entertain any demand/claim.
- (i) After completion of supplies, the documents related to tax invoice, test reports of supplied batches or any other document shall be submitted to APMSIDC for proper acknowledgement of stocks. Supplier need to upload all the required details in eAushadhi portal prior to supply to CDS. APMSIDC will not be responsible for any delay in uploading the documents by the supplier which may lead to unforeseen penalties or any wrong entries due to typographical errors.
- (j) It is the duty of the supplier to supply Drugs/Medicines at the 13 CDS in AP or any other place decided by APMSIDC and supply shall conform to the conditions mentioned in the provisions of tender documents, viz., logo, nomenclature, specification etc. having a minimum of 3/4th of the shelf life
- (k) .APMSIDC reserves the right to place up to 50% additional purchase order of the quantities as contracted within validity of contract.

SUPPLY CONDITIONS

- Purchase orders will be issued to the Tenderer(s) at the discretion of the APMSIDC as per actual requirements. All the supplies shall be received at the 13 CDS in AP or any other place decided by APMSIDC.
- Within 4 days from the receipt of purchase orders, the Tenderer should inform APMSIDC through eAushadhi for the receipt of the purchase order.
- The Tenderer should also Communicate and mail the details of supply dates as specified in Annexure, to APMSIDC within 7 days from the receipt of the purchase order. In case, the supply shall not be made by the date as conveyed by the supplier, supply order shall be cancelled at their risk and cost. If no response is received within 7 days from the supplier / tenderer about supply of

surgical consumables as per purchase order, it shall be presumed that the supplier/tenderer is not interested to supply the surgical consumables ordered as per purchase order and APMSIDC shall purchase the surgical consumables from alternative sources.

- Supplies against a purchase order shall be completed within **60 days** otherwise liquidated damages are levied by APMSIDC as mentioned in clause 18.1.
- If the Tenderer fails to execute the supply within the stipulated time, the APMSIDC is at liberty to make alternative arrangement for purchase of the items for which the Purchase orders have been placed, from any other sources or in the open market or from any other Tenderer who might have quoted higher rates, at the risk and the cost of the defaulted supplier and in such cases the APMSIDC has every right to recover the cost and impose Liquidated Damages as mentioned in Clause 18. In case of any variation in prices during alternative procurement will be charged to L1 bidder or defaulted supplier.
- The liquidated damages as specified in clause 18.1 and 18.2 of the tender conditions will be levied. However, the supplier must take prior approval from APMSIDC for supply of Surgical and consumables beyond stipulated delivery period in Purchase order.
- The Tenderer must submit an Analysis report for every batch of surgical consumables along withinvoice. In case of failure on part of the supplier to furnish such report, the batch of surgical consumables will be returned to the suppliers and he is bound to replenish the same with Govt. approved lab test report. The Surgical Consumables supplied by the successful Tenderer shall be of the best quality and shall comply with ISO/BIS/CE and the specifications specified in the tender.
- If at any time the Tenderer has, in the opinion of the APMSIDC delayed the supply of surgical consumables due to one or more reasons related to Force Majeure events such as riots, mutinies, wars, fire, storm, tempest, floods or other exceptional events at the manufacturing premises, the time for supplying the surgical consumables may be extended by the APMSIDC at discretion for such period as may be considered reasonable. However, such extension shall be considered only if a specific written request is made by the Tenderer within 20 days from the date of occurrence of such event with necessary documentary evidence. The exceptional events do not include the Increase in the cost of raw material, Electricity failure, Labour disputes/Strikes, Insolvency, and Closure of the Factory/Manufacturing unit on any grounds etc.
- The supplier shall not be liable to pay LD and forfeiture of performance security deposit for the delay in executing the contract on account of the extension of supply period on the ground of force majeure events.

 If the product is not consumed prior to its expiry date i.e., six months before expiry,

the supplier will be notified about the short expiry surgical consumables upon receipt of such information the supplier should replace (at own cost of supplier to and fro) the short expiry/expired quantity with fresh stock of longer shelf life, otherwise the value equal to the cost of expired quantity will be deducted from the bills or any other amount payable to the firm.

LOGOGRAMS

Logogram means, wherever the context occurs, the design as specified in ANNEXURE-I. The name of the product shall be mentioned in English /Telugu as per pharmacopoeia and its strength.

- Tenders for the supply for Surgical and consumables., shall be considered only if the Tenderer gives an undertaking that the product(s) will be prepared as per the specifications such as name, strength, minimum size and packed with appropriate size as per the design enclosed as per ANNEXURE –I.
- Failure to supply Surgical and consumables with the printed logogram of proportionate size will be treated as breach of the terms of price agreement / violation of tender conditions. The purchase order shall be cancelled at the risk and cost of the supplier. However, if such failure continuous despite notice, will be viewed as a serious lapse and APMSIDC will initiate suitable action.
- For imported surgical consumables, the supplies will be accepted as per packing and label by foreign manufacturer in their brand subject to affixing sticker for Logo as approved by APMSIDC.

PACKING

- The supplier shall provide such packing of the goods as is required to prevent their damage or deterioration during transit to their final destination as indicated in the contract. The packing shall be sufficient to withstand, without limitation, rough handling during transit and exposure to extreme temperatures, salt and precipitation during transit and open storage. Packing case size and weights shall take into consideration.
- The packing, marking and documentation within and outside the packages shall comply strictly with such special requirements, as shall be provided for in the contract and subject to clause 18 and any subsequent instructions ordered by the purchaser.

QUALITY TESTING

- Samples of supplies from each batch will be chosen at the point of dispatch at supplier's site or receipt of supply or distribution/storage points for testing at discretion of APMSIDC. The samples will be sent to different laboratories including Government Drugs Testing Laboratory/NIPER/PSU labs for testing as decided by the APMSIDC. Handling and testing charges will be borne by APMSIDC for the above purpose.
- In the event, if the samples fails in quality tests or found to be not as per specifications, APMSIDC is at liberty to make alternative purchase of the items of items for which the Purchase orders have been placed from any other sources or in the open market or from any other Tenderer who might have quoted higher rates, at the risk and the cost of the supplier and in such cases the APMSIDC has every right to recover the cost and impose penalty as mentioned in Clause 19.
- The supplier shall furnish evidence of the basis for shelf life and other stability data concerning the commercial final package on request by the APMSIDC. In case of any complaint in the field, the B.M.R/B.P. R for the particular batch of the product(s) supplied shall be produced when demanded.
- The products should conform to the standards of ISO/BIS/CE/ISI as the case may be. In case the product is not included in the any of the said compendiums, the supplier, upon award of the contract, must provide the reference standards and testing protocols for quality control testing. For imported products, respective Country.

PAYMENT PROVISIONS

- No advance payments towards costs of surgical consumables will be made to the Tenderer.
- Payments towards the supply of surgical consumables will be made within 60 days from the date of receipt of goods, as per the tender terms and condition. The payment will be made through AP Government Finance portal CFMS / RTGS (Real Time Gross Settlement System)/Core Banking/NEFT. The Tenderer shall furnish the relevant details in original (MANDATE FORM) to make the payment through CFMS/RTGS/Core Banking/NEFT.
- All bills/Invoices should be raised in duplicate and the bills should be drawn as per GST Rules in the name of MD, APMSIDC. Mangalagiri, Andhra Pradesh.

(i)Payment of 50% for a given purchase order will be made after completion of 75% supplies of ordered quantity and remaining will be paid after completion of 95% of supplies. In case any purchase order is executed partially beyond 75% up to 95% remaining bills will be processed at the discretion of APMSIDC by imposing a penalty of 10% on unexecuted quantity value only.

(ii) The payment for part supply if any will subject to the deduction of liquidated damages, penalty towards unexecuted quantity, risk and cost etc., as per the tender conditions.

- If at any time during the period of contract, the price of tendered items is reduced or brought down by any law or Act of the Central or State Government or by the Tenderer himself, the Tenderer shall be bound to inform the APMSIDC immediately about such reduction in the contracted prices. Tender Inviting Authority is empowered to unilaterally effect such reduction as is necessary in rates in case the Tenderer fails to notify or fails to agree for such reduction of rates.
- In case of any increase or decrease in the GST after the date of submission of tenders and during the tender period, such variation in the GST will be to the account of the APMSIDC. For claiming the additional cost on account of the increase in GST, the Tenderer should produce the proof of having paid additional amount on this account on the goods supplied to APMSIDC from the concerned authorities and also must claim the same in the invoice separately.
 - However, the basic price structure and the price of the surgical approved under the tender shall not be altered. Similarly, if there is any reduction in the GST as notified by the Govt., after the date of submission of tender, the Tenderer will be paid based on the unit rate worked out on the basis of the reduced GST without any change in the basic price or the price structure of the surgical approved under the tender. Any increase or decrease in GST will be considered based on the notification issued by the Government.
 - However, if the firm supplies after originally stipulated delivery period, increase in GST shall be borne by the supplier. In case of decrease in taxes/GST due to statutory variation in taxes/GST, the same shall be passed on by the supplier to the APMSIDC.
 - Subject to the conditions mentioned in the Purchase Order, Tender Document, Price Agreement and here under, the Supplier is entitled for the payment against supply. In case of any discrepancy in levy of LD, Penalty, Unexecuted Fine, Short Passing of Bills, such discrepancy shall be intimated within 30 days from the date of receipt of payment.

TESTING CHARGES:

In all supplies, testing charges will be borne by APMSIDC as per the Batch sizes provided by Firm. For Excess batches beyond their batch size confirmation will be charged double testing charges from their payable bills.

LIQUIDATED DAMAGES AND OTHER PENALTIES:

| Category of Products | Stipulated supply period as per Tender clause | % of Penalties | |
|----------------------|---|--|--|
| | 60 days | Nil | |
| | 60 to 75 Days | 0.5% per day. | |
| Surgical consumables | 76 to 90 Days | The supply period can be extendable for another 15 days beyond 76 days upon request @ 0.5% per day.At sole discretion of MD,APMSIDC. | |

- * The maximum amount of liquidated damages shall be maximum 10%.
- * Beyond 90 days if the PO is not executed, the PO will be deemed to be cancelled and the firm will be declared as undependable.
- If the supply is received in damaged condition, open delivery of the supplies shall be received, wherein it is possible to physically inspect the shipment, damaged products shall not be accepted.
- All the Tenderers are required to supply the product(s) with printed "Andhra Pradesh Govt. Supply – Not for Sale" and logogram of appropriate size. If there are any deviations in this condition, action will be taken to blacklist the product and/or a separate damage will be levied @ 5% of value of the defaulted quantity irrespective of the Tender Inviting Authority having actually suffered any damage/loss or not, without prejudice the rights of alternative purchase specified in Clause No.14.11 and 13.4. Imported products can be exempted from this condition.

DEDUCTION & OTHER PENALTIES ON ACCOUNT OF QUALITYFAILURE:

• If the samples do not conform to statutory standards, the Tenderer will be liable for relevant action under the existing laws and the entire stock in such batch has to be taken back by the Tenderer within a period of 30 days of the issue of the

letter from the APMSIDC Such stock shall be taken back at the expense of the Tenderer. Further, actual testing charges (including handling charges for conducting those tests) shall be paid to APMSIDC by the supplier otherwise these charges shall be recovered from their pending bill/EMD/performance security deposit. The APMSIDC has the right to destroy such "NOT OFSTANDARD QUALITY" if the Tenderer does not take back the goods within the stipulated time.

- The decision of the APMSIDC or any officer authorized by him, as to the quality
 of the supplied surgical consumables shall be final and binding. In such cases,
 the APMSIDC will be at liberty to terminate, the contract either wholly or in part
 on 30 days' notice. The Tenderer will not be entitled for any compensation
 whatsoever in respect of such termination besides forfeiture of Performance
 Security Deposit.
- For contravention of the stipulations of the contract or for other justifiable reasons, the contract may be terminated by the APMSIDC, and the Tenderer shall be liable to pay for all losses sustained by the APMSIDC in consequence of the termination which may be recovered from the Tenderer, as per rules besides forfeiture of Performance Security Deposit.
- Non-performance of any of the contract conditions and provisions will disqualify a firm from participating in the tender for the next 2 years besides forfeiture of Performance Security Deposit.
- In the event of making Alternative Purchase, as specified in Clause 12.4 (a), Clause 14.11 and in Clause 15.3 penalty will be imposed on the supplier. The excess expenditure over and above contracted prices incurred by the APMSIDC in making such purchases from any other sources or in the open market or from any other Tenderer who has quoted higher rates and other losses sustained in the process, shall be recovered from the Performance Security Deposit or from any other money due and become due to the supplier and in the event of such amount being insufficient, the balance will be recovered personally from the supplier as per rules.
- In all the above conditions, the decision of the MD, APMSIDC shall be final and binding.

BLACKLISTING IN THE EVENT OF WITHDRAWL FROM THE TENDER, AND NON-ADHERENCE TO THE QUALITY STANDARDS AND SUPPLY SCHEDULE

BLACKLISTING OF PRODUCT/TENDERER ON WITHDRAWAL OF TENDER

If the Tenderer(s) fails to perform the obligations under the tender conditions / commits default in the performance of the contract, such Tenderers will be blacklisted for a period of 2 years by APMSIDC from the date of observing the defect besides forfeiture of Performance security deposit.

BLACKLISTING FOR QUALITY FAILURE

QUALITY TEST BY THE EMPANELLED LABORATORIES OF APMSIDC

- a. Each batch of supplied surgical consumables shall be subjected to quality test by the empanelled laboratories.
- b. The samples collected from each batch of supply of each surgical consumable will be sent to the empanelled testing laboratories for testing the quality of surgical consumables. In addition to the above APMSIDC hall also draw the samples of products supplied to the health facilities and get the same tested, to make sure the products are conforming to quality requirements.
- c. If sample passes quality tests in all respects, APMSIDC will instruct its CDS to release such items for usage.
- d. If the sample of any batch fails in quality test and report is received stating Not of Standard Quality such batch of product shall be rejected.
- e. If the supplier challenges and requests for retesting after an NSQ is received from empanelled laboratory (other than Government Laboratory), the other portion of the same batch shall be sent to State Drugs Control Laboratory, AP or any other Government testing laboratory or NABL accredited laboratory as decided by APMSIDC. The test report received from any of these laboratories (second opinion) will be final for any decision and will be binding to the supplier. The cost of such retesting shall be recovered from the supplier.

If two batches of item supplied by the same supplier is reported to be NOT OFSTANDARD QUALITY (NSQ) in specifications as given in table under clause 20.2.2(b), then the product of the firm shall be blacklisted for 2 years after observing procedure laid down in Para 20.2.3.

QUALITY TEST BY STATUTORY AUTHORITIES:

a. If any item is declared "NOT OF STANDARD QUALITY", by any of the Government testing laboratory (DCL, AP or CDTLs or NIB, Noida or any other Government labs), the issue of available stock of the particular item will be stopped. Further, the available stock of the product in hospitals/CDS will be retrieved.

b.

| S.No (A) | Formulation (B) | Test Parameters in which sample fails I | No. of Batches that fail the test (D) |
|-------------|----------------------|---|--|
| 1 | Surgical consumables | Failing in test for Sterility, Fungal Growth | 01 |
| | consumables | Any other parameter | 02 |
| 2 | Diagnostic kits | Incorrect result | 02 |

As per the above table if number of batches of same product (shown in column D) of a particular firm are declared as NSQ in tests shown in above table then that particular surgical consumable of the firm will be blacklisted against the firm for a period of 2 years.

The amount of the NSQ batch shall be deducted/ withheld from the amount payable to the firm or from the performance security deposit of the firm. No purchase orders will be placed for the blacklisted item of the firm.

- c. In case a firm is supplying more than one product and one of the products is declared as NSQ, in such case, in addition to the measure suggested above, 10% of total bill amount submitted by the firm will be withheld for a period of four months and will be paid after monitoring satisfactory supply of all other products.
- d. If two items of any firm are blacklisted, then the entire firm will be blacklisted, and it will not be allowed to participate in tender for 2 consecutive years from the date of blacklisting.
- e. If any batch of any product(s) supplied by the company/firm declared, NOT OF STANDARD QUALITY in specification by the Government Authorities during the relevant tender period or during quality check within shelf life period, suitable action will be taken for blacklisting of the product/ firm.

PROCEDURE FOR BLACKLISTING:

 On receipt of complaint from CDS or report from Govt. Analyst/Drug Testing Laboratory indicating that a particular Item is "NOT OF STANDARD QUALITY" (As the case may be), a show cause notice shall be issued to the supplier calling for explanation within 7 days from the date of notice. On receipt of explanation from the supplier, the MD, APMSIDC may take appropriate action on merits of the case and impose penalty including the blacklisting of the item of the product/company or firm as deemed fit besides forfeiture of Performance Security Deposit.

- If a particular product has been blacklisted according to the procedure stated above, the supplier is not eligible to participate in any of the tenders for that particular item floated by the APMSIDC until the period of blacklisting is over.
- If a supplier company/firm is blacklisted according to the procedure stated above, such supplier is not eligible to participate in any of the tenders floated by the APMSIDC until the period of blacklisting is over.

BLACKLISTING FOR NON-SUPPLY:

Due to non-supply of item against any purchase order, 5 % value of purchase order shall be recovered from the supplier in addition of other penal like risk purchase. In case of repeated circumstances of non-supply of items i.e. 3times, the supplier may be blacklisted for 2 years in addition of forfeiture of Performance Security Deposit/ EMD and other penal action.

APPEAL (s) IN CASE OF BLACKLISTING:

I. A supplier/firm whose product or the supplier/firm, itself have been blacklisted by the corporation which is displayed in the corporation website i.e.://msidc.ap.nic.in// may within 15 days from the date of display, may appeal to the Director General, Drug Control Administration, A.P.

The Director General, Drug Control Administration, A.P., after such enquiry into the matter, as is considered necessary and after giving the said supplier an opportunity for representing his views, may pass such order in relation thereto, as he thinks fit.

II. If the firm is not satisfied with the outcome may appeal within 15 days to the Principle Secretary, Health, Medical & Family Welfare, A.P. for review. The State Government after such enquiry into the matter, as is considered necessary and after giving the said supplier an opportunity for representing his views, may pass such order in relation thereto, as it thinks fit.

SAVING CLAUSE

No suit, prosecution or any legal proceedings shall lie against the Tender Inviting Authority or any person for anything that is done in good faith or intended to be done in pursuance of the tender. APMSIDC reserves the right to make modification, alteration or relaxation in any of the clauses or conditions given in this tender document.

RESOLUTION OF DISPUTES

The APMSIDC and the supplier shall make every effort to resolve, amicably by direct informal negotiation any disagreement or dispute arising between them under or in connection with the contract.

FRAUDULENT AND CORRUPT PRACTICES:

For bidders:

If the APMSIDC determines that a Supplier has engaged in corrupt, fraudulent, collusive, coercive or obstructive practices, in competing for or in executing the Contract, then the APMSIDC may, after giving 7 days' notice to the Supplier, terminate the Supplier's engagement under the Contract and cancel the contract, and the procurement will be made at the risk and cost of the supplier besides blacklisting the bidder for 2 years with forfeiture of Performance security deposit apart from other penal actions.

It is purchaser's policy to ensure that suppliers and their authorized representatives/agents observe the highest standard of ethics during the procurement and execution of such contracts. (In *this context, any action taken by a bidder, supplier, contractor, or by their authorized representatives/agent, to influence the procurement process or contract execution for undue advantage is improper*) In pursuance of this policy, the purchaser;

- (a) defines, for the purposes of this provision, the terms set forth below as follows:
 - i."corrupt practice" is the offering, giving, receiving or soliciting, directly or indirectly, of anything of value to influence improperly the actions of another party ("another party" refers to a public official acting in relation to the procurement process or contract execution]. In this context, "public official" includes staff and employees of other organizations taking orreviewing procurement decisions.
 - ii. "fraudulent practice" is any act or omission, including a misrepresentation, that knowingly or recklessly misleads, or attempts to mislead, a party to obtain a financial or other benefit or to avoid an obligation (a "party" refers to a public official; the terms "benefit" and "obligation" relate to the procurement process or contract execution; and the "act or omission "is intended to influence the procurement process or contract execution).
 - iii. "collusive practice" is an arrangement between two or more parties designed to achieve an improper purpose, including to influence improperly the actions of another party ["parties "refers to participants in the procurement process

(including public officials) attempting to establish bid prices at artificial, noncompetitive level].

- iv."coercive practice" is impairing or harming, or threatening to impair or harm, directly or indirectly, any party or the property of the party to influence improperly the actions of a party (a"party" refers to a participant in the procurement process or contract execution).
- v."obstructive practice" is

(a) deliberately destroying, falsifying, altering or concealing of evidence material to the investigation or making false statements to investigators in order to materially impede an investigation into allegations of a corrupt, fraudulent, coercive or collusive practice; and/or threatening, harassing or intimidating any party to prevent it from disclosing its knowledge of matters relevant to the investigation or from pursuing the investigation; or acts intended to materially impede the exercise of the purchaser's inspection and audit rights provided for under sub-clause (e) below.

- (b) will reject a proposal for award if it determines that the bidder considered for award has, directly or through an agent, engaged in corrupt, fraudulent, collusive, coercive or obstructive practices in competing for the contract in question;
- (c)will cancel the contract if the purchaser determines at any time that the bidder, supplier and contractors and their sub-contractors engaged in corrupt, fraudulent, collusive, or coercive practices.
- (d)will sanction a firm or individual, including declaring in eligible, either indefinitely or for a stated period of time, to be awarded a contract if it at any time determines that the firm has, directly or through an agent, engaged in corrupt, fraudulent, collusive, coercive or obstructive practices in competing for, or in executing, a contract; and
- (e) will have the right to inspect the accounts and records of the bidders, supplier, and contractors and their subcontractors/authorized representatives and to have them audited by auditors appointed by the purchaser.

JURISDICTION

In the event of any dispute arising out of the tender such dispute would subject to the jurisdiction of the Honorable Civil Courts within the city of Vijayawada only.

FORCE MAJEURE

• For purposes of this clause "Force Majeure" means an event beyond the control of the supplier and not involving the supplier's fault or negligence and not fore-see-able. Such events may include but are not limited to, acts of the

purchaser either in its sovereign or contractual capacity, wars or revolutions, floods, epidemics, quarantine restrictions and freight embargoes.

 If a force majeure situation arises, the supplier shall promptly notify the purchaser in writing of such conditions with documentary evidence and the cause thereof. Unless otherwise directed by the purchaser in writing the supplier shall continue to perform its obligations under the contract as far as is reasonably practical and shall seek all reasonable alternative means for performance not prevented by the force majeure event. APMSIDC :: DRUGS WING ANNEXURE –I DESIGN FOR LOGOGRAMS SPECIMEN LABEL FOR OUTER CARTON AND INNER INDIVIDUAL PACK OF THE PRODUCT A.P. GOVT. SUPPLY NOT FOR SALE (or) DECLARATION

I do hereby declare that I will supply the surgical consumables as per the above design.

Signature

<u>ANNEXURE -II</u> (On nonjudicial Stamp Paper)

Ref. Clause No. 4.1(a)

DECLARATION

I/We M/s..... represented by its Proprietor/Managing Partner /Managing Director having its registered office at and its factory premises at do hereby declare as under: -

(I) that I/we have carefully read all the terms and conditions of tender in ref. no. including Amendment(s) to Tender document (if any) issued by APMSIDC, Mangalagiri and accept unconditionally all terms and condition of tender document including Amendment(s) to Tender document (if any).

(II) I/We hereby declare that all required annexures and documents are uploaded.

(III) lam / We are aware of the Tender inviting Authority's right to forfeit the Earnest Money Deposit and /or Performance security deposit and blacklist me/us for a period of 2 years if, any information furnished by us proved to be false at time the of inspection and also not complying with any of the tender conditions.

Name of the bidder:

Address:

Name of the authorized signatory:

Sign and Seal:

ANNEXURE-III

AFFIDAVIT FOR NON BLACKLISTING

| l | | | | N | lanaging Direc | ctor/Director | ctor / |
|-----------------------|------------|------------|---------------|-------------|-----------------|---------------|--------|
| Partner / Proprie | etor of I | M/s | | | | having | j its |
| manufacturing | or | import | unit | / | registered | c | office |
| at | | | | | do he | ereby de | clare |
| that the firm & its o | quoted pro | oduct have | not been bla | acklisted | currently (as o | n the da | te of |
| submission of the | tender) I | by Central | Governmen | t/Central | Government A | Agencies | /any |
| state government | /any of | the state | government | agencie | es/any Drug | Procure | nent |
| Agencies or by A | PMSIDC | . We are | eligible to p | participate | e for the follo | wing qu | oted |
| products. | | | | | | | |

| S.No | Tender S.No | ltem Code | ltem Name | Whether Manufactu rer/Importer | Mfg. /Import License No. And Date | Date of issue of product approval BY licensing authority | Mfg./Import License and product approval valid up to |
|------|----------------|--------------|--------------|--------------------------------------|---|---|--|
| | | | | | | | |

Date:

Signature Seal:

(Authorised Signatory) Name and Address of the Bidder

ANNEXURE-IV

Ref. Clause No.4.1(b)

{Format for a certificate from the C.A. (Chartered Accountant) or Company Secretary}

(I) It is certified that M/s..... is a Private. /Ltd./Proprietorship/Partnership company/firm and they have PAN no and GST registration no.... They have filed Income tax returns and GST returns up to date. The authorized signatory of the company/firm is Shri and whose signature is attested asunder:

(II) The annual Turnover of M/s.....for the past three years i.e. 2017-18, 2018-19 and 2019-20 **or** 2018-19, 2019-20 and 2020-21 are given below and certified that the statement is true and correct.

| S. No | Financial Year | Turnover in Lakhs (Rs.) |
|---------|----------------------|-------------------------|
| 1 | | |
| 2. | | |
| 3. | | |
| TOTAL | | RsLakh |
| Average | e Turnover per annum | RsLakh |

(III)...... It is certified that M/s...... has Production &financial capacity to manufacture and deliver the Surgical Consumables quoted by them in the tender as per quantity & delivery schedule mentioned in tender. This certificate is based on their Manufacturing capacity, inventory of raw Material and financial statement.

Or **(ONLY in case of IMPORTER)** It is certified that M/s..... has Financial capacity to manufacture and deliver the surgical consumables quoted by them in the tender as per quantity &delivery schedule mentioned in tender. This certificate is based on their Manufacturing capacity, inventory of raw Material and financial statement.

Or **(ONLY in case of SSI/MSME Manufacturer of AP)** It is certified that M/S ________ is Micro and Small Enterprises (MSE)/SSI and registered with Director of Industries appropriate authorities for quoted products against APMSIDC tender No. _______ and eligible for exemption of paying EMD.

Date_____

(Name, Signature & Stamp) Registration no.

ANNEXURE-V

STATEMENT OF CAPACITY OF PRODUCTION

01. Name of the firm:

Address

The installed capacity of this firm is as follows per shift

Name of the product Capacity

| S. No | ltem Code | Name of the Product | Batch Size | Manufacturing/ importing capacity per 60 days |
|----------|--------------|------------------------|------------|---|
| 1 | | | | |
| 2 | | | | |

Signature of the tenderer: _____ Date _____

Full Name (IN BLOCK LETTERS) _____

NOTE: - Details are to be provided for two month's production capacity

Signature and seal of the Tenderer_____

CHECK-LIST

(Documents to be Uploaded)

| S. N | Check List | YES | NO | PAGE |
|------|--|-----|----|------|
| 1 | Processing Fee The bidder shall remit processing fee Rs. Rs. 11,800/- (NON REFUNDABLE) in the form of DD in the name of The Managing Director, APMSIDC, Mangalagiri/NEFT/RTGS. | | | |
| 2 | EMD Rs. 3,00,000/- in the form of Demand Draft / NEFT/ RTGS/ Online Uploaded NSIC or MSME certificate of AP state for exemption if any. | | | |
| 3 | Scanned copy of Valid ISO/BIS/CE/ISI Certificate of manufacturing company. In case of imported products, scanned copy Valid quality Certificate of manufacturing company of foreign company. | | | |
| 4 | Scanned copy of Valid manufacturing/import/distributor License for the Product. (For items notified as Drugs it is from DCA and for Non-Drug items it is from concerned statutory Departments).(Non drugs-authorization from manufacture and manufacture licence) If pesticides and larvicides licence issued by Agriculture department. | | | |
| | Scanned copy of Valid Import License, if Imported and wholesale Drug license | | | |
| | Scanned copy of valid Non-Conviction Certificate issued by the licensing authority/ Self declaration in Company letter head as per tender document. | | | |
| 7 | Scanned copy of ANNEXURE -II (Declaration for eligibility in participating the tender) original Annexure II delivered to APMSIDC. | | | |
| 8 | Scanned copy of ANNEXURE IV Certificate from the C.A. (Chartered Accountant) or Company Secretary. | | | |
| 9 | Details for Manufacturing Capacity & Batch Size Annexure V | | | |
| 10 | Scanned copy of ANNEXURE-VII (Mandate form) | | | |

NOTE: -EMD instrument and Processing Fee are to be delivered in original to APMSIDC, Mangalagiri on or before stipulated dates give in document.

Name and signature of authorized signatory (with company seal).

MANDATE FORM (ANNEXURE VII)

| S.No. | Details Required | | |
|-------|-------------------------------|--------------|--|
| 1. | Company Name | | |
| | PAN Number | | |
| | TIN Number | | |
| | GST NO. | | |
| | Date of Inception | | |
| | Legal status of the Bidder | | |
| | (Proprietorship/ Partnership/ | | |
| | Pvt. Ltd. Company/ Limited | | |
| | Company) | | |
| | License No. & Date | | |
| | Issued By | | |
| | Valid Up to | | |
| 2. | Postal Address of the | | |
| | Company | | |
| | Telephone No. | | |
| | Fax No. | | |
| | E-mail ID | | |
| | Alternate E-mail ID | | |
| 3. | Name of the Managing | | |
| | Director / Director / Manager | | |
| | Mobile No. / Phone No | | |
| | E-mail ID | | |
| 4. | Name and Designation of the | Name: | |
| | authorized company official | Designation: | |
| | Mobile No. | | |
| | E-mail ID | | |
| 5. | Bank Details | | |
| | a) Name of the Bank | | |
| | b) Branch Name & address | | |
| | c) Branch Code No. | | |
| | d) Branch Manager Mobile | | |
| | No. | | |
| | e) Branch Telephone no | | |
| | f) Branch E-mail ID | | |
| | g) 9-digit MICR code number | | |
| | of the bank and branch | | |
| | appearing on the MICR | | |
| | cheque issued by the bank | | |
| | Branch | | |
| | h) Type of Account (Current / | | |
| | Savings) | | |

| S.No. | Details Required | |
|-------|-----------------------------|--|
| | i)Account Number (as appear | |
| | in cheque book) | |

(In lieu of the bank certificate to be obtained, please upload the original cancelled cheque issued by your bank for verification of the above particulars).

I / We hereby declare that the particulars given above are correct and complete. If the transaction is delayed or not effected at all the reasons of incomplete or incorrect information, I would not hold APMSIDC responsible. I have read the conditions of the tender / Price agreement and agree to discharge the responsibility expected of me / from the company as a tenderer / successful tenderer.

Date: Place:

Company Seal.....Signature (Name of the person signing & designation)

CERTIFIED THAT THE PARTICULARS FURNISHED ABOVE BY THE COMPANY ARE CORRECT AS PER OUR RECORDS.

TENDER ITEMS ANNEXURE-VIII

| S No | Item Name | Specification | Tentative quantity required | Program |
|---------|--|--------------------------------|-----------------------------------|---------|
| 1 | RT-PCR (open) Testing Kit for Hepatitis B Virus | Provided in Tender Document | 1309 | NVHCP |
| 2 | RT-PCR (open) Testing Kit for Hepatitis C Virus | Provided in Tender Document | 3155 | NVHCP |

<u>Note :</u> Quantities mentioned are tentative, PO quantity may increase or decrease as per requirement.

samples for each item quoted has to be submitted for sample verification by the end of the Bid submission date with offline documents. HBV PCR Kit 1.5 contains the following components:

| Lid Color | HBV 1.5 Component | Number of Tubes | Nominal Volume [µl/Tube] | |
|-----------|----------------------|-----------------|-----------------------------|--|
| Blue | Master A | 8 | 240 | |
| Purple | Master B | 8 | 300 | |
| Red | QS1* | 2 | 550 | |
| Red | QS2* | 2 | 550 | |
| Red | QS3* | 2 | 550 | |
| Red | QS4* | 2 | 550 | |
| White | NTC** | 2 | 550 | |

Table 1: Kit Components

* Quantification Standard

**No Template Control

Storage:

- All components of the -15 °C upon arrival.
 HBV PCR Kit 1.5 must be stored between -25 °C and
- After thawing, Master A and Master B are stable for 5 hours at up to +30 °C.
- After thawing, the QS and the NTC are stable for 5 hours at up to +30 °C.

Performance Evaluation:

The performance evaluation of the HBV PCR Kit 1.5 was performed using the 4th WHO International Standard for HBV DNA for Nucleic Acid Amplification Techniques (NIBSC code: 10/266) and HBV standard material calibrated against the WHO International Standard.

Internal Control IC:

If the IC is used as a control for the sample preparation procedure and as a PCR inhibition control, the IC has to be added during the nucleic acid extraction procedure. No matter which method/system is used for nucleic acid extraction, the IC **must not** be added directly to the specimen. The IC should always be added to the specimen/lysis buffer mixture. The volume of the IC which has to be added depends always and only on the elution volume. It represents 50% of the elution volume. For instance, if the nucleic acid is going to be eluted in 90 μ l of elution buffer or water, 45 μ l of IC per sample must be added into the specimen/lysis buffer mixture. If added in the master-mix, IC volume would be 0.83 μ L.

The

Reaction Setup:

| 1x | |
|---------|--|
| 6.66ul | |
| 8.33ul | |
| 0.83ul | |
| 15.82ul | |
| | |

| Full Volume | 1x |
|------------------|------|
| Master Mix | 15ul |
| Sample / Control | 15ul |
| Total Volume | 30ul |

Temperature Profile and Dye Acquisition:

| Settings | | |
|-------------------|---------|--|
| Ramp Rate | Default | |
| Passive Reference | ROX™ | |

| Detection | Detector Name | Reporter | Quencher |
|------------------|---------------|----------|----------|
| HBV specific DNA | HBV | FAM™ | (None) |
| Internal Control | IC | VIC™ | (None) |

| | Stage | Cycle Repeats | Acquisition | Temperature | Time |
|----------------------|-----------------|---------------|-------------|-------------|----------|
| Denaturation | Hold | 1 | - | 95 °C | 2:00 min |
| Dendrardare | tine di Station | | | 95 °C | 0:15 min |
| Amplification | Cycling | 45 | V | 58 °C | 0:45 min |
| Ampinication Cycinig | | - | 72 °C | 0:15 min | |

Validity of a Diagnostic PCR Run:

A diagnostic PCR Run is valid, if the following control conditions are met:

Control conditions for a valid PCR Run

| Control ID | FAM™ Detection Channel | VIC™ Detection Channel |
|-----------------------|---------------------------|---------------------------|
| Positive Control (QS) | POSITIVE | POSITIVE |
| Negative Control | NEGATIVE | POSITIVE |

Result validity

| Sample ID | FAM™ Detection Channel | VIC™ Detection Channel | Result Interpretation |
|--------------|---------------------------|---------------------------|--|
| A | POSITIVE | POSITIVE* | HBV specific DNA detected. |
| в | NEGATIVE | POSITIVE | HBV specific DNA not detected. Sample does not contain detectable amounts of HBV specific DNA. |
| с | NEGATIVE | NEGATIVE | PCR inhibition or reagent failure. Repeat testing from original sample or collect and test a new sample. |

* Detection of the Internal Control in the VIC[™] detection channel is not required for positive results in the FAM[™] detection channel. A high hepatitis B virus load in the sample can lead to reduced or absent Internal Control signals.

Standard curve control parameter

| Control Parameter | Valid Value |
|----------------------------|-----------------|
| Slope | - 3.00 / - 3.74 |
| PCR Efficiency | 85 % / 115 % |
| R square (R ²) | > 0.98 |

The limit of detection of the HBV PCR Kit 1.5 for the detection of HBV in EDTA plasma is 10.2 IU/ml (95 % confidence interval: 7.6 - 15.8 IU/ml). The linear range of the HBV PCR Kit 1.5 for the quantification of HBV in EDTA plasma is 20 - 10,000,000 IU/ml.

To determine the viral load of the original sample, use the following formula:

Viral load (Sample) [IU/ml] =

Volume (Eluate) [µl] x Viral load (Eluate) [IU/µl]

Sample Input [mi]

HCV RT-PCR Kit 1.5 contains the following components:

| Lid Color | HCV 1.5 Component | Number of Tubes | Nominal Volume [µl/Tube] |
|-----------|----------------------|-----------------|-----------------------------|
| Blue | Master A | 8 | 240 |
| Purple | Master B | 8 | 300 |
| Red | QS1* | 2 | 550 |
| Red | QS2* | 2 | 550 |
| Red | QS3* | 2 | 550 |
| Red | QS4* | 2 | 550 |
| White | NTC** | 2 | 550 |

* Quantification Standard

**No Template Control

Storage:

- All components of the and -15 °C upon arrival.
 HCV RT-PCR Kit 1.5 must be stored between -25 °C
- After thawing, Master A and Master B are stable for 5 hours at up to +30 °C.
- After thawing, the QS and the NTC are stable for 5 hours at up to +30 °C.

Quantification Standards:

The Quantification Standards (QS) contain standardized concentrations of HCV specific RNA (see Table 2). They were calibrated against the 5th WHO International Standard for HCV NAT (NIBSC code: 14/150). The Quantification Standards are used to verify the functionality of the HCV RNA specific amplification and detection system as well as to generate a standard curve, which allows the quantification of HCV specific RNA in a sample.

| Quantification Standard | Concentration [IU/µI] |
|-------------------------|-----------------------|
| QS1 | 1.00E+04 |
| QS2 | 1.00E+03 |
| QS3 | 1.00E+02 |
| QS4 | 1.00E+01 |

The

Internal Control IC:

If the IC is used as a control for the sample preparation procedure and as a PCR inhibition control, the IC has to be added during the nucleic acid extraction procedure. No matter which method/system is used for nucleic acid extraction, the IC **must not** be added directly to the specimen. The IC should always be added to the specimen/lysis buffer mixture. The volume of the IC which has to be added depends always and only on the elution volume. It represents 50% of the elution volume. For instance, if the nucleic acid is going to be eluted in 90 μ l of elution buffer or water, 45 μ l of IC per sample must be added into the specimen/lysis buffer mixture. If added in the master-mix, IC volume would be 0.83 μ L.

Reaction Setup:

| No. of reactions | 1x |
|-------------------|---------|
| Master A | 6.66ul |
| Master B | 8.33ul |
| IC | 0.83ul |
| Volume Master Mix | 15.82ul |

| Full Volume | 1x |
|------------------|------|
| Master Mix | 15ul |
| Sample / Control | 15ul |
| Total Volume | 30ul |

Temperature Profile and Dye Acquisition:

| Sett | ings | |
|-------------------|---------|--|
| Ramp Rate | Default | |
| Passive Reference | ROX™ | |

| Detection | Detector Name | Reporter | Quencher | |
|------------------|---------------|----------|----------|--|
| HCV specific RNA | HCV | FAM™ | (None) | |
| Internal Control | IC | VICTN | (None) | |

| | Stage | Cycle Repeats | Acquisition | Temperature | Time |
|--------------------------|-------|---------------|-------------|-------------|-----------|
| Reverse Transcription | Hold | 1 | - | 55 °C | 20:00 min |
| Denaturation | Hold | 1 | - | 95 °C | 2:00 min |
| | | | | 95 °C | 0:15 min |
| Amplification Cycling | 45 | √ | 55 °C | 0:45 min | |
| | | - | 72 °C | 0:15 min | |

Validity of a Diagnostic PCR Run:

A diagnostic PCR Run is valid, if the following control conditions are met:

Control conditions for a valid PCR Run

| Control | Detection Channel | | |
|--|-------------------------------|-------------------------|--|
| | FAM [™] (HCV target) | VIC™ (Internal Control) | |
| Quantification Standard (Std / Pos) | + | not applicable | |
| NTC | - | + | |

Result validity

| Detection Channel | | Becult Validity | |
|-------------------|-------------------------|-----------------|--|
| FAM™ (HCV target) | VIC™ (Internal Control) | Result Validity | |
| + | • | Valid result | |
| + | | Valid result* | |
| - | + | Valid result | |
| - | | Invalid result | |

* Detection of the Internal Control is not required when the HCV target is detected. A high HCV RNA load in the sample can lead to a reduced or absent Internal Control signal.

Standard curve control parameter

| Control Parameter | Valid Value |
|----------------------------|-----------------|
| Slope | - 3.00 / - 3.74 |
| PCR Efficiency | 85 % / 115 % |
| R square (R ²) | > 0.98 |

The limit of detection of theHCV RT-PCR Kit 1.5 for the detection of HCV in EDTAplasma is 11.1 IU/ml (95 % confidence interval: 7.8 - 18.5 IU/ml). The linear range of the

HCV RT-PCR Kit 1.5 for the quantification of HCV in EDTA plasma is 25 - 10,000,000 IU/ml.

To determine the viral load of the original sample, use the following formula:

| Viral load (Sample) [IU/ml] = | Volume (Eluate) [µl] x Viral load (Eluate) [IU/µl] | |
|-------------------------------|--|--|
| | Sample Input [mi] | |